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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,967	12/26/2001	Shigeru Kamei	087147-0443B	2213

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EXAMINER	
LUKTON, DAVID	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/025,967	KAMEI ET AL.	
	Examiner	Art Unit	
	David Lukton	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 16-25* is/are pending in the application.

4a) Of the above claim(s) *4-10 and 17-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Pursuant to the directives of the response filed 12/27/05, claim 1 has been amended and claims 11-15 cancelled. Claims 1-10 and 16-25 remain pending. Claims 4-10 and 17-25 remain withdrawn from consideration. Claims 1-3 and 16 are examined in this Office action.

Applicants have requested (page 7 of the response filed 12/27/05) that the examiner indicate whether or not the foreign priority documents have been received by the examiner of 10/025,967, or are otherwise available. In response, the PTO-326 accompanying this Office action provides a definitive response to this question.

Applicants' arguments filed 4/14/05 have been considered and found persuasive in part.

✧

Claims 1-3 and 16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,480,868. Although the conflicting claims are not identical, they are not patentably distinct from each other. Applicants have not traversed this rejection, so it is maintained without further comment.

✧

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in

the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 16 is rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have asserted that the compound of claim 16 is an LH-RH antagonist. However, there is no evidence that this is the case. Certainly, other antagonists of LH-RH are known. But the reality in pharmacology is that one cannot "predict" receptor antagonism or even receptor binding merely be viewing the structure of a compound. Minor changes in structure can result in elimination of activity. As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims.

Given the unpredictability of structure/activity relationships, "undue experimenation" would be required of the skilled artisan to use the composition of claim 16 to antagonize LH-RH.

In response to the foregoing, applicants have argued that examiners are barred from imposing enablement rejections in cases where the asserted utility is not specifically recited **in the claim**. In response, the examiner would opine that applicants' reading of the case law is somewhat bizarre. If applicants believe that such a court opinion exists, applicants should cite it. The instant specification asserts (e.g., page 8, line 5+) that the compounds (to which the claims are directed) are LHRH antagonists, and may be useful for treating certain LHRH-dependent diseases. If applicants believe that there is some other asserted utility for the compound at issue, applicants should point out the location in the text where the assertion may be found.

The rejection is maintained.

✧

Claim 1 is objected to.

First, the structural formula is not clearly legible. Applicants' intentions with regard to the claimed invention must be clear to the persons responsible for printing the final document.

Second, there is another typographical issue. The following is recited in claim 1:

"wherein $R_{3'}$ is a heterocyclic group; R_5 represents a group of the formula - - $(CH_2)_n$- - $R_{5'}$"

Here, a **single** hyphen should be used to denote a covalent bond. The same error may be found two lines below (in claim 1) the phrase at issue.

✧

The following is a quotation of 35 U.S.C. §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1-3 are rejected under 35 U.S.C. §103 as being unpatentable over Haviv (USP 5,110,904) in view of Deasy (USP 4,874,612) or Hutchinson (USP 4,789,726).

As indicated previously, Haviv discloses (cols 12-25) various peptides falling within the scope of instant claim 1. Also disclosed (col 27, line 8+) is that the peptide can be combined with a PLA/PLG copolymer. Haviv does not suggest selecting a polydispersity that is somewhere in the range of 1.2-4.

Each of the secondary references discloses PLA/PGA copolymers that have the requisite polydispersity. For example, this is disclosed in Deasy at col 2, line 45+.

Hutchinson even goes a step further in arguing (col 2, line 51+; col 3, line 53+) that a polydispersity of about 2 is the most statistically probable distribution of molecular weights. A practitioner of the Haviv invention may or may not see an advantage in a polydispersity of 2, but would recognize that such a composition is most likely to be obtained.

Thus, the claims are rendered obvious.

✦

Claims 1-3 are rejected under 35 U.S.C. §103 as being unpatentable over Haviv (USP 5,110,904) in view of Boswell (USP 3,773,919) further in view of either Deasy (USP 4,874,612) or Hutchinson (USP 4,789,726).

The teachings of Haviv and Boswell were indicated previously. The teachings of Deasy (USP 4874612) and Hutchinson (USP 4789726) are indicated above.

Thus, Haviv provides a "roadmap" to Boswell, and a practioner of the resulting invention would have been motivated to use the PLA/PGA polymers of Deasy for the advantages cited therein, or the inevitable polydispersity of 2 cited in Hutchinson.

Thus, the claims are rendered obvious.

✦

Those references stricken from the IDS were not received, and are not present in any of the parent application files. In addition, no translations of foreign documents have been received. For each foreign patent document, it is suggested that, for each abstract provided, applicants list the following under the "other documents" section

Abstract of xxxx

This will make the record clear that only the abstract was considered, and not the full document.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached at 571-272-0925. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

D. Lukton

DAVID LUKTON, PH.D.
PRIMARY EXAMINER